

## **REMARKS**

### **Status of the Claims**

Claims 2, 4-10, 24-43, 49-60, 63-66, 68-75 were pending. As shown above, claims 2 and 4 have been amended to return to previous claim language making it explicit that the Gag polypeptide encoded by the claimed polynucleotide elicits a Gag-specific immune response (*see, also*, Example 4). In addition, claims 2 and 4 have been amended to make explicit that the claimed polynucleotide sequences must exhibit at least 90% sequence identity to the full-length of SEQ ID NOs:3 or 4.

Thus, claims 2, 4-10, 24-43, 49-60, 63-66, 68-75 are pending as shown above.

### **Priority**

The Office Action acknowledges that the claims have priority to the application filed September 1, 1999. (Office Action, page 2).

### **Rejections Withdrawn**

Applicants note with appreciation that the obviousness-type double patenting rejection over application no. 09/967,464 have been withdrawn. (Office Action, page 3). In addition, the rejection under 35 U.S.C. § 112, 1<sup>st</sup> paragraph (enablement) has been withdrawn. (Office Action, page 7).

### **Obviousness-Type Double Patenting**

Claims 2, 4, 41, 68, 69 and 74 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 6,602,705. (Office Action, page 3). Claims 7-10, 24-40 and 71-73 were also rejected as allegedly obvious over claims 4, 11, 12, and 14-30 of U.S. Patent No. 6,602,705. (Office Action, page 4).

In addition, claims 2, 4, 5, 7, 41, 68 and 70 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 7,211,659. (Office Action, page 4). Claims 49, 50, 51, 52, 54, 55, 56, 67 and 58 were

rejected under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over claims 35, 36, 40, 41, 43, 37, 38, 39, 44 and 45 of U.S. Patent No. 7,211,659. (Office Action, page 5).

Applicants submit the appropriate terminal disclaimer herewith, thereby obviating these rejections.

**35 U.S.C. § 112, 1<sup>st</sup> paragraph, written description**

The rejection of claims 2, 4, 7-10, 24-43 and 49-60 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph as allegedly not adequately described by the as-filed specification was maintained. (Office Action, pages 6-7). In particular, it was maintained that the claims encompass polynucleotides that encode Gag proteins that elicit non-specific immune responses and that “the specification does not disclose a correlation between the structure of the polynucleotides and the desired biological activity.” (Office Action, page 6 and page 7, 3<sup>rd</sup> full paragraph).

The pending claims are drawn to polynucleotides that encode Gag polypeptides and further specify that the Gag polypeptides elicit a Gag-specific immune response. Thus, the claims do not encompass polynucleotides that encode polypeptides that elicit a non-specific immune response.

Moreover, Applicants strongly traverse the assertion that the “specification” does not disclose a correlation between the structure of the polynucleotides and the desired biological activity. For the reasons detailed extensively throughout the lengthy prosecution of this application, the as-filed specification more than adequately describes how the polynucleotides as claimed encode Gag polypeptides that generate a Gag-specific immune response. Indeed, working examples (see, Example 4) showing how SEQ ID NOs:3 and 4 encode immunogenic HIV Gag polypeptides and elicit Gag-specific immune responses are provided. Thus, as-filed specification fully describes polynucleotides encoding polypeptides with the biological activity recited in the pending claims.

Furthermore, while Applicants completely agree that the claims are drawn to polynucleotides, the Office’s previous rejections have been based on the allegation that the Gag polypeptides encoded by the claimed polynucleotides have many diverse functions that were not necessarily present in the encoded polypeptides. (Office Action, page 7, 1<sup>st</sup> full paragraph).

Accordingly, Applicants have repeatedly noted that the claims are directed only to polynucleotides encoding Gag-specific immunogenic polypeptides and, as such, other functions of Gag polypeptides are not relevant.

In sum, the skilled artisan, having followed the teaching of the specification, would have no doubts that Applicants were in possession of the claimed subject matter. Accordingly, for all the reasons of record and those set forth herein, the as-filed specification more than satisfies the written description requirement of 35 U.S.C. § 112, 1<sup>st</sup> paragraph and withdrawal of the rejection is respectfully requested.

### **35 U.S.C. § 102(b)**

Claims 2, 4, 24, 25, 27, 39, 40 and 41 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Schwartz et al. (1992) *J. Virol.* 66:7176-7128 (hereinafter “Schwartz”). (Office Action, pages 8-9). Schwartz was alleged to teach sequences of approximately 20 nucleotides within GenBank Accession No. L04602 that exhibit 90% sequence identity to fragments of the same length within SEQ ID NOs:3 and 4. (Office Action, page 9).

The pending claims are directed to polynucleotides having at least 90% sequence identity to full-length SEQ ID NO:3 or SEQ ID NO:4. As shown in the attached alignments, GenBank Accession No. L04602 as disclosed in Schwartz exhibits only 67% identity to full length SEQ ID NO:3 and 62% identity to full length SEQ ID NO:4.

Thus, Schwartz does not describe or demonstrate polynucleotides as claimed and withdrawal of the rejection is in order.

### **35 U.S.C. § 103(a)**

Claims 7-10 and 24-29 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Schwartz in view of Persson et al. (1998) *Biologicals* 26:255-265. (Office Action, pages 9-12). Schwartz was cited as above and Persson was cited for teaching various modifications of an HIV expression construct encoding HIV protease and polymerase. *Id.* It was alleged that it would have been obvious to combine Schwartz’s Gag-encoding polynucleotides with Persson’s prot- and pol-encoding nucleotides and that such a combination would result in the claimed polynucleotides. *Id.*

For the reasons detailed above and has shown in the attached alignments, Schwartz in now way teaches or suggests polynucleotides having at least 90% identity to full length SEQ ID NO:3 or SEQ ID NO:4. As admitted by the Office, Persson also fails to teach such polynucleotides. Accordingly, there is no combination of these references that would result the claimed subject matter.

For at least these reasons, the rejection of claims 7-10 and 24-29 under 35 U.S.C. § 103(a) cannot be sustained.

**CONCLUSION**

In light of the above amendments and remarks, Applicants submit that the present application is in condition for allowance. If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned.

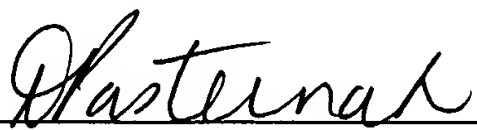
The Commissioner is hereby authorized to charge any fees and credit any overpayment of fees which may be required under 37 C.F.R. §1.16, §1.17, or §1.21, to Deposit Account No. 18-1648.

Please direct all further written communications regarding this application to:

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Respectfully submitted,

Date: January 23, 2008

By:   
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## ClustalW Results

Results of search

Number of sequences	2
Alignment score	1520
Sequence format	Pearson
Sequence type	nt
ClustalW version	1.83
JalView	<a href="#">Start JalView</a>
Output file	<a href="#">clustalw-20071114-00154024.output</a>
Alignment file	<a href="#">clustalw-20071114-00154024.aln</a>
Guide tree file	<a href="#">clustalw-20071114-00154024.dnd</a>
Your input file	<a href="#">clustalw-20071114-00154024.input</a>

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## Scores Table

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SeqA Name	Len(nt)	SeqB Name	Len(nt)	Score
1 seqidno3	1479	2 genbankL04602	336	67

PLEASE NOTE: Some scores may be missing from the above table if the alignment was done using multiple CPU mode. Please check the output.

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## Alignment

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CLUSTAL W (1.83) multiple sequence alignment

```
seqidno3      ATGGGCGCCCGCGCCAGCATCCTGCGCGGCGGCAAGCTGGACGCCTGGGAGCGCATCCGC 60
genbankL04602 -----

seqidno3      CTGCGCCCGCGGCAAGAAGTGCTACATGATGAAGCACCTGGTGTGGGCCAGCCGCGAG 120
genbankL04602 TTAAGGCCAGGGGAAAGAAGTACAAGCTAAGCACATCGTATGGGCAAGCAGGGAG 60
* * * * *

seqidno3      CTGGAGAAGTTGCCCCTGAACCCCGGCTGCTGGAGACCAGCGAGGGCTGCAAGCAGATC 180
genbankL04602 CTAGAACGATTGCGAGTTAATCCTGGCCTGTTAGAAACATCAGAAGGCTGTAGACAAATA 120
* * * * *

seqidno3      ATCCGCCAGCTGCACCCCGCCCTGCAGACCGGCGAGGAGCTGAAGAGCCTGTTCAAC 240
genbankL04602 CTGGACAGCTACAACCATCCCTTCAGACAGGATCAGAGGAGCTTCGATCACTATAAAC 180
* * * * *

seqidno3      ACCGTGGCCACCTGTACTGCGTGACAGAGAAGATCGAGGTCCGCGACACCAAGGAGGCC 300
genbankL04602 ACAGTAGCAACCTCTATTGTGTGCACAGCGGATCGAGATCAAGGACACCAAGGAAGCT 240
* * * * *

seqidno3      CTGGACAAGATCGAGGAGGAGCAGAAACAAGTGCCAGCAGAAGATCCAGCAGGCCGAGGCC 360
genbankL04602 TTAGACAAGATAGAGGAAGAGCAAAACAAGTCCAAGAAGAGGCCAGCAGGCAGCAGCT 300
* * * * *

seqidno3      GCCG-----ACAAGGGCAAGGTGAGCCAGAACTACCCCATCGTGCAGAACCTGCAGGGC 414
genbankL04602 GACACAGGACACAGCAATCAGGTCAGCCAAAATTAC----- 336
* * * * *

seqidno3      CAGATGGTGCACAGGCCATCAGCCCCCGCACCCCTGAACGCCTGGGTGAAGGTGATCGAG 474
genbankL04602 -----

seqidno3      GAGAAGGCCTTCAGCCCCGAGGTGATCCCCATGTTACCGCCCTGAGCGAGGGCGCCACC 534
genbankL04602 -----

seqidno3      CCCAGGACCTGAACACGATGTTGAACACCGTGGGCGGCCACAGGCCCATGCAGATG 594
genbankL04602 -----

seqidno3      CTGAAGGACACCATCAACGAGGAGGCCGCCGAGTGGGACCGCGTGCACCCCGTGCACGCC 654
genbankL04602 -----

seqidno3      GGCCCCATCGCCCCCGGCCAGATGCGCGAGCCCCCGGCGAGCATCGCCGGCACCAACC 714
genbankL04602 -----
```

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genbankL04602 -----

seqidno3      ATCTACAAGCGGTGGATCATCTGGGCTGAACAAGATCGTGCGGATGTACAGCCCCGTG 834
genbankL04602 -----

seqidno3      AGCATCCTGGACATCAAGCAGGGCCCCAAGGAGCCCTTCCGCGACTACGTGGACCGCTTC 894
genbankL04602 -----

seqidno3      TTCAAGACCTGCGCGCCGAGCAGAGCACCCAGGAGGTGAAGAACTGGATGACCGACACC 954
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seqidno3      CGCGTGCTGGCCGAGGCGATGAGCCAGGCCAACACCAGCGTGATGATGAGAAGAGCAAC 1134
genbankL04602 -----

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genbankL04602 -----

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seqidno3      GGCCGCCCCGGCAACTTCTGCAGAGCCGCCCCGAGCCACCGCCCCCGCGGAGAGC 1374
genbankL04602 -----

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genbankL04602 -----

seqidno3      ACCAGCCTGAAGAGCCTGTTGGCAACGACCCCTGAGCCAGTAA 1479
genbankL04602 -----
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#### Guide Tree

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(seqidno3:0.16220,genbankL04602:0.16220);

#### Cladogram

seqidno3  
genbankL04602

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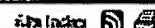


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## ClustalW Results

Results of search

Number of sequences	2
Alignment score	1790
Sequence format	Pearson
Sequence type	nt
ClustalW version	1.83
JalView	
Output file	<a href="#">clustalw-20071114-23101942.output</a>
Alignment file	<a href="#">clustalw-20071114-23101942.aln</a>
Guide tree file	<a href="#">clustalw-20071114-23101942.dnd</a>
Your input file	<a href="#">clustalw-20071114-23101942.input</a>

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## Scores Table

[View Output File](#)

SeqA Name	Len(nt)	SeqB Name	Len(nt)	Score
1 seqidno4	1509	2 genbankL04602	396	62

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[View Output File](#)

## Alignment

[Show Colors](#)[View Alignment File](#)

CLUSTAL W (1.83) multiple sequence alignment

```
seqidno4      ATGGGCGCCCGCGCCAGCATCTGCGCGGCGAGAAGCTGGACAAGTGGGAGAAGATCCGC 60
genbankL04602 ATGGGTGCGAGAGCGTCAGTATTAAAGCGGGGAGAATTAGATCGATGGGAAAAAATTCGG 60
*****

seqidno4      CTGCGCCCCGCGGCAAGAAGCACTACATGCTGAAGCACCTGGTGTGGGCCAGCCGCGAG 120
genbankL04602 TTAAGGCCAGGGGAAAGAAGTACAAGCTAAAGCACATCGTATGGGCAAGCAGGGAG 120
*****

seqidno4      CTGGAGGGCTTCGCCCTGAACCCCGGCTGCTGGAGACCGCGAGGGCTGCAAGCAGATC 180
genbankL04602 CTAGAACGATTTCGAGTTAATCCTGGCCTGTAGAAACATCAGAAGGCTGTAGACAAATA 180
*****

seqidno4      ATGAAGCAGCTGCAGCCCGCCTGCAGACCGGCACCGAGGAGCTGCGCAGCCTGTACAAC 240
genbankL04602 CTGGGACAGCTACAACCATCCCTTCAGACAGGATCAGAGGAGCTTCGATCACTATACAAC 240
*****

seqidno4      ACCGTGGCCACCTGTACTGCGTGACGCCGCGCATCGAGGTCCGCGACACCAAGGAGGCC 300
genbankL04602 ACAGTAGCAACCTCTATTGTGTGCACCGCGGATCGAGATCAAGGACACCAAGGAAGCT 300
*****

seqidno4      CTGGACAAGATCGAGGAGGAGCAGAACAAGTCCCAGCAGAAGCCAGCAGGCCAAGGAG 360
genbankL04602 TTAGACAAGATAGAGGAAGAGCAAAACAAGTCCAAGAAGAAGGCCAGCAGGC---AGCA 357
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seqidno4      GCCGACGGCAAGGTGAGCCAGAACTACCCCATCGTGACAGAACTGCAGGGCCAGATGGTG 420
genbankL04602 GCTGACA-----CAGGACACAGCAATCAGGTCA-GCCAAAATTAC----- 396
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genbankL04602 -----

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genbankL04602 -----

seqidno4      ACCATCAACGAGGAGGCCGCGAGTGGGACCGCCTGCACCCCGTGCAGGCCGCGCCCGTG 660
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seqidno4      GCCCCCGGCCAGATGCGCGACCCCGCGGCGAGCGACATCGCCGGCGCCACCAGCACCTG 720
genbankL04602 -----
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seqidno4      CAGGAGCAGATCGCCTGGATGACCAGCAACCCCCCGTGGCCGTGGGCGACATCTACAAG 780
genbankL04602 -----

seqidno4      CGGTGGATCATCCTGGGCCTGAACAAGATCGTGGGATGTACAGCCCGTGAGCATCCTG 840
genbankL04602 -----

seqidno4      GACATCCGCCAGGGCCCCAAGGAGCCCTTCGCGACTACGTGGACCGCTTCTTCAAGACC 900
genbankL04602 -----

seqidno4      CTGCGCGCCGAGCAGGCCACCCAGGACGTGAAGAACTGGATGACCGAGACCCTGCTGGTG 960
genbankL04602 -----

seqidno4      CAGAACGCCAACCCCGACTGCAAGACCATCCTGCGCGCTCTCGGCCCCGGCGCCACCCTG 1020
genbankL04602 -----

seqidno4      GAGGAGATGATGACCGCCTGCCAGGGCGTGGGCGGCCCGGCCACAAGGCCCGCTGCTG 1080
genbankL04602 -----

seqidno4      GCCGAGCGATGAGCCAGGCCAACAGCGTGAACATCATGATGCAGAAGAGCAACTTCAAG 1140
genbankL04602 -----

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seqidno4      TGCCGCGCCCCCGCAAGAAGGGCTGCTGGAAGTGGCGCAAGGAGGGCCACCAGATGAAG 1260
genbankL04602 -----

seqidno4      GACTGCACCGAGCGCCAGGCCAACTTCCTGGGCAAGATCTGGCCAGCCACAAGGGCCGC 1320
genbankL04602 -----

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genbankL04602 -----

seqidno4      CCCGCCGAGAGCTTCCGCTTCGAGGAGACCACCCCGCCCCCAAGCAGGAGCCCAAGGAC 1440
genbankL04602 -----

seqidno4      CGCGAGCCCTACCGCGAGCCCCTGACCGCCCTGCGCAGCCTGTTGGGCGAGCGGCCCTG 1500
genbankL04602 -----

seqidno4      AGCCAGTAA 1509
genbankL04602 -----
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(seqidno4:0.18813,genbankL04602:0.18813);

#### Cladogram

seqidno4  
genbankL04602

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Show Distances

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